

# China Brings E-Cigarettes Under its Tobacco Monopoly Law: Will This Reshape the Global Industry?

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The tobacco industry in China, which is home to more than 300 million cigarette smokers, is controlled by the largest tobacco company in the world – the China National Tobacco Corporation (CNTC). The CNTC’s dominant global market share is almost entirely the result of its monopoly of the domestic Chinese tobacco industry. When fulfilling its regulatory role, CNTC is also referred to as the State Tobacco Monopoly Administration (STMA), which is a government-granted monopoly established by China’s Tobacco Monopoly Law. Under the Tobacco Monopoly Law, STMA maintains control over virtually all stages of the production, sales, import, export, and distribution of tobacco products in China. The Tobacco Monopoly Law (Article 2) historically extended STMA’s monopoly control to the following traditional tobacco and tobacco-related products: cigarettes, cigars, cut tobacco, redried leaf tobacco, leaf tobacco, cigarette paper, filter rods, filter tows, and equipment exclusively for use in the manufacture of tobacco products.

Finally, after [years](#) of [speculation](#), on November 26, 2021, China’s State Council published online its final decision to amend the [Implementing Regulation of the Tobacco Monopoly Law](#), which makes e-cigarettes subject to the same monopoly requirements as traditional, combustible cigarettes. The STMA and China’s Ministry of Industry and Information Technology (MIIT) first proposed the amendment in March 2021, highlighting their belief that “e-cigarettes and traditional cigarettes are homogeneous in terms of core ingredients, product functions, and consumption methods.”

Specifically, a new Article 65 is added to the Implementing Regulation as follows: “(The management of) Novel tobacco products such as e-cigarettes are implemented with reference to the relevant requirements for cigarettes in this Regulation.” This new article essentially puts all “novel” tobacco products, including e-cigarettes, under the same monopoly as cigarettes with respect to the manufacture, sales, import and export, etc. However, this single-sentence amendment does not provide any details as to how exactly the existing monopoly system on cigarettes in China will apply to e-cigarettes.

In furtherance of the amended Implementing Regulation, on December 2, 2021, the STMA published

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on its website the draft [Management Rules for E-cigarettes](#) for public comment.

The draft Management Rules define “e-cigarette” as an electronic delivery product that produces nicotine-containing aerosol for human inhalation. The definition does not include “heated cigarettes” (i.e., heat-not-burn tobacco products) that are already regulated as cigarettes and subject to the Tobacco Monopoly Law. The draft Management Rules make clear that e-cigarettes should be regulated like tobacco products by STMA and its local agencies and provide that e-cigarettes must comply with the e-cigarette National Standard (see more details below). Notably, pre-market registration of e-cigarettes is required upon a safety review by STMA. In addition to pre-market registration requirements, the production and sales of e-cigarettes in China will be subject to the same tobacco monopoly licensing as traditional cigarettes.

According to the draft Management Rules, a unified national e-cigarette trading platform will be set up by STMA, and the producers and sellers must trade on that platform, including imported e-cigarettes. The draft Management Rules also contain various requirements designed to protect minors such as age-restrictions and generally require that relevant warning and labeling requirements must be met.

## **Registration and Production Licensing Requirements for Chinese Manufacturers**

The regulation of e-cigarettes in China is of critical importance to the global e-cigarette industry, as the vast majority (over 95%) of e-cigarette hardware, including devices and components and parts, are manufactured in Shenzhen. Many of these companies operate solely for the purpose of original equipment manufacturers (OEMs) manufacturing products for sale not in China, but around the world. Under the draft Management Rules, however, *all* Chinese e-cigarette manufacturing facilities are subject to the registration and production licensing requirements, even if the products produced are ultimately for export only.

## **GB Standard on E-Cigarettes**

As we previously [reported](#), in 2019, China notified the World Trade Organization (WTO) about the first draft national Guobiao (GB) Standard on e-cigarettes. On November 30, 2021, STMA published the [updated draft GB Standard](#) for comment.

Compared with the previous version, the draft GB Standard, entitled “Electronic Cigarette,” is shortened from 68 pages to 26 pages. The structure of the draft GB Standard and a brief description of the content are as follows:

- Section 1 – **Scope**
- Section 2 – **Referenced standards**
- Section 3 – **Definitions**. This section provides the definition for electronic cigarettes which is basically the same as the draft Management Rules. E-vapor matters, e-liquids, e-cigarette devices, e-cigarette modules, cartridges, etc., also are defined.
- Section 4 – **Design and raw materials**. This section focuses on the general safety of the device and raw materials. For example, materials in contact with the mouth, e-vapor matters, and e-cigarette emissions must meet the requirements of food contact materials, nicotine must be extracted from tobacco with a purity of no less than 99%, etc.

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- Section 5 – **Technical requirements**. This section provides technical requirements for the key risk points of e-cigarettes, e-vapor matters, etc. For example, the concentration of nicotine in e-vapor matters must not exceed 20 mg/kg. Limitations on 2,3-butanedione, heavy metals (as Pb) and arsenic (as As) in e-vapor matters, as well as limitations on carbonyl compounds in e-cigarette emissions, are also provided in this section.
  - Section 6 – **Testing methods**
  - Section 7 – **Labeling and accompanying documents**
  - Appendix A – **List of exceptions to the restricted substances in e-cigarette materials**
  - Appendix B – **Substances temporarily permitted for use as additives in e-vapor matters**
  - Appendices C through F – **Determination methods, etc.**

## **Transition Period**

In view of the new regulations and the GB Standard, on December 2, 2021, STMA [announced](#) a transition period from now until the finalization and implementation of the Management Rules and the GB Standard. It is not clear now when they will be finalized and implemented, but STMA indicated in the announcement for the draft GB Standard that the plan is to implement the GB Standard “three to five months after its publication.”

Specifically, during the transition period, the existing e-cigarette production and operation enterprises can continue to carry out production and operation activities. However, investors are not allowed to invest in newly established e-cigarette production and operation enterprises; existing e-cigarette production and operation entities are not allowed to build or expand production capacity, establish new e-cigarette retail outlets, and market new products. “New import of e-cigarettes” will also be suspended during this period.

STMA also publicizes a “e-cigarette information reporting system” on its [website](#) and urges e-cigarette production and operation enterprises to report information about the enterprise and the products from December 6 to December 21, 2021.

## **Comment Periods Closing Soon**

The public comment period for the draft Management Rules closes on [December 17, 2021](#), fifteen days after its publication, and the public comment period for the draft Standard closes on [January 29, 2022](#).

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National Law Review, Volume XI, Number 340

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